ABSTRACT OF THE DISCLOSURE

This invention relates to detection of specific extracellular nucleic acid in plasma or serum fractions of human or animal blood associated with neoplastic or proliferative disease. Specifically, the invention relates to detection of nucleic acid derived from mutant oncogenes or other tumor-associated DNA, and to those methods of detecting and monitoring extracellular mutant oncogenes or tumor-associated DNA found in the plasma or serum fraction of blood by using rapid DNA extraction followed by nucleic acid amplification with or without enrichment for mutant DNA. In particular, the invention relates to the detection, identification, or monitoring of the existence, progression or clinical status of benign, premalignant, or malignant neoplasms in humans or other animals that contain a mutation that is associated with the neoplasm through detection of the mutated nucleic acid of the neoplasm in plasma or serum fractions. The invention permits the detection of extracellular, tumor-associated nucleic acid in the serum or plasma of humans or other animals recognized as having a neoplastic or proliferative disease or in individuals without any prior history or diagnosis of neoplastic or proliferative disease. The invention provides the ability to detect extracellular nucleic acid derived from genetic sequences known to be associated with neoplasia, such as oncogenes, as well as genetic sequences previously unrecognized as being associated with neoplastic or proliferative disease. The invention thereby provides methods for early identification of colorectal, pancreatic, lung, breast, bladder, ovarian, lymphoma and all other malignancies carrying tumor-related mutations of DNA and methods for monitoring cancer and other neoplastic disorders in humans and other animals.